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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,545	03/28/2001	John kung	JBP0547	3384

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EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/819,545

Applicant(s)

KUNG ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-60 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Amendment filed on May 21, 2003 has been entered. Claims 47-60 are pending. This application contains claims 47-48 drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 49-60 are under consideration. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment.

#### ***Double Patenting***

2. Claims 27-46 stand provisionally rejected under the judicially created doctrine of double patenting over claims 24-25, 27-30, 34-37 of copending Application No. 09/341,426 for the reasons of record. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

#### ***Claim Rejections - 35 USC § 103***

3. Claims 49-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Froix et al US Patent 5,851,538, in view of Simon et al US Patent 5,730,972.

4. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that Froix's compositions are directed to retinoids that are encapsulated or trapped in microporous spheres.

5. In reply Examiner states that the instant claims do not exclude such features with respect to the retinol. Therefore, Applicant's arguments are not commensurate with the scope of the claims and are considered moot.

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6. Further, Examiner points out that the instant claims are directed to compositions comprising an amount of a composition consisting essentially of ascorbic acid-2-glucoside, Acrylates/C0-30 Acrylate cross polymers and retinol. The scope of the instant claim does not in no way exclude existence of other types of ingredients that are taught in Froix or Simon. Examiner views the instant claims to contain any type of compound so long as ascorbic acid-2-glucoside, Acrylates/C0-30 Acrylate cross polymers and retinol exists in the final composition. There is no requirement in the instant claims that the penetration-enhancing composition keeps its integrity in the final topical composition that is instantly claimed. In another word, the penetration enhancing composition can be a solution containing ascorbic acid-2-glucoside, acrylate copolymers and retinol, which can be combined with other conventional compounds to form the instantly claimed topical composition. Therefore, Applicant's attempt to limiting the scope of the claims to compositions consisting essentially of ascorbic acid-2-glucoside, Acrylates/C0-30 Acrylate cross polymers and retinol is improper.

7. Further, Applicant's reliance on the results set forth in Table 1 and 2 of the specification has been fully considered but are not found persuasive, because the analysis is not commensurate with the scope of pending claimed topical compositions. Namely, the instant compositions are not limited to the components of composition B, C, or D of the Table 1 and 2.

8. Froix et al teach topical skin formulations of Retinoid suspended in esters of acrylic or methacrylic polymers (see col 4 lines 14-25, claims 1, 5-10) in combination with antioxidants such as ascorbic acid (vitamin C) to lower the irritancy caused by

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retinoids when applied on skin (see example II, and claim 1-10). Froix et al however do not specifically use a sugar ester of ascorbic acid in their composition.

9. Simon et al disclose compositions for combating skin marks comprising at least one sugar such as ascorbyl-2-glucoside, and a UVA screening agent (see abstract, claim 1 and 5). The composition of Simon et al also comprise a polymeric emulsifier such as Pemulen, a polyethylene alcohol such as polyethylene glycol stearate, and a moisturizing agent such as glycerol (see col 7-9; examples 2-4). Simon specifically states that ascorbic acid glucoside is highly water soluble and is converted to Vitamin C when administered to skin (see col 2, lines 51-60).

10. Both Froix and Simon teach methods of enhancing topical delivery of active agents, therefore, their teachings are viewed as being in the same field of endeavor.

Although Froix does not use an ascorbic acid glycoside in his compositions, it would have obvious to one of ordinary skill in the art at the time of invention to modify Froix's composition by using any ascorbic acid precursor of Simon et al in place of vitamin C, because as stated by Simon, the ordinary skill in the art would have expected the ascorbic acid glycoside to convert to vitamin C and lead to lower irritation of retinol.

Further, Froix teaches that the combination of Vitamin C and retinoid together in a composition improves the skin irritation caused by retinoids, thus, the ordinary skill in the art would have had a reasonable expectation to reduce skin irritation of retinoids when administering it with any Vitamin C derivative. Accordingly, substituting Vitamin C with its art equivalent, ascorbic acid glycoside, would have been obvious.

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Finally, absence of using unexpected results, optimizing the concentrations of individual ingredients is well within the scope of a skilled artisan, therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Froix composition to contain ascorbic acid glycoside, as taught by Simon, and further optimize the concentrations by routine experimentation for their respective pharmacological effects.

11. Claims 27-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al US Patent 6,544,531 in view of Simon et al US Patent 5,730,972.

Cole teaches retinol compositions comprising retinol, acrylate C10-30 Alkyl Acrylate, and a ascorbyl glucoside (see abstract, Examples 5-6, claims 1-2, 4). Cole does not teach the use of ascorbic acid glycoside.

Simon provides for the use of ascorbic acid glycoside.

12. As it is well known in the art that ascorbic acid derivatives can improve the irritability of retinol, it would have been obvious to one of ordinary skill in the art at the time of invention to use ascorbic acid -2-glycoside of Simon in place of the ascorbic acid sources of Cole, because the ordinary skill in the art would have expected the same functional properties from ascorbic acid-2-glycoside of Simon. Furthermore, absence of showing the criticality, optimizing the concentrations of the ingredients in such compositions would have been attainable by routine experimentation.

### ***Conclusion***

13. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

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**FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss  
August 7, 2003

  
**RUSSELL TRAVERS**  
**PRIMARY EXAMINER**  
**GROUP 1200**